

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/573,753	<b>Applicant(s)</b> CEBON ET AL.	
	<b>Examiner</b> MARIANNE DIBRINO	<b>Art Unit</b> 1644	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 02 August 2010. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 20-22, 25, 26 and 34-37.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☒ Other: 'See continuation on next page'.

/Ram R. Shukla/  
Supervisory Patent Examiner, Art Unit 1644

/DiBrino Marianne/  
Examiner, Art Unit 1644

Continuation of 3. NOTE: the amendment of base claim 20 is a new issue that would require further consideration and search. In addition, said amendment adding "in a ratio of about 1:1 by weight" is new matter, since the support for said amendment cited by Applicant in Example 1 of the instant specification is to two species, i.e., a ratio of 10:12 and a ratio of 1:1, falling within the genus of "in a ratio of about 1:1 by weight" represented by the proposed amendment. Applicant has support for the two disclosed species, but not the genus. In addition, said proposed amendment would raise 112, 2<sup>nd</sup> paragraph issues, as Applicant has not redefined the term "about" in the specification.

Continuation of 13. Other: Applicant's arguments as to the proposed claim set will not be addressed herein. The Examiner will address Applicant's remaining arguments that may pertain to the pending claim set.

Concerning the 102 rejection of record, Applicant's arguments are directed to points already addressed by the Examiner in the last Advisory Action of record mailed 7/12/10, but it is noted that Applicant's response to the request for information under 37 CFR 1.105 establishes that the slides that are cited in the said 102 rejection were part of a virtual meeting accessible to virtual meeting registrants and that the in vivo trial represented by the slides corresponds to Example 1 of the application (which disclosure meets the proposed amendment to the claims).

Applicant's arguments on pages 7-8 at section A have already been addressed and are of record.

With regard to Applicant's arguments at section B on page 8, Applicant is arguing Jager separately as previously discussed by the Examiner, i.e., Batchu et al teach that CD8+ T cell responses can be produced to help reduce the risk of relapse by eradicating residual tumor cells, while Jager et al teach peptides that can induce CD9+ T cell responses to the NY-ESO-1 protein. With regard to Applicant's argument about 4/5 patients developing additional lesions, Applicant does not point to the portion of Jager that Applicant relies on. However, the Examiner notes that Jager et al differentiate the antibody-negative patients from the antibody-positive patients, and 5/7 of the patients in the former group developed stabilization or regression of individual metastases (paragraph spanning columns 1-2 on page 12201) that was associated with CD8+ T cell responses, providing evidence of a reasonable expectation of success in producing the claimed invention by combining the cited references.

The Examiner has previously responded to Applicant's arguments at section C on page 9 about Cebon, and the Examiner's comments on Jager apply herein.

With regard to Applicant's section V on pages 9-10, Applicant's arguments as to Cebon have been addressed by the Examiner, Batchu teaches that CD8+ T cell responses can be produced to help reduce the risk of relapse by eradicating residual tumor cells, and the combination of Batchu with other references has also been addressed by the Examiner. Regarding Applicant's argument about modified DCs in Batchu et al, Batchu teaches that identification of tumor-specific immunogenic antigens has been a problem, but Batchu also teaches that NY-ESO-1 has been identified as a tumor-specific antigen that elicits both MHC class II-mediated CD4+ Th T cell and MHC class I-mediated CD8+ CTL responses, both of which "make it an excellent choice for CTL induction." Applicant's argument pertaining to Jager has been addressed supra. Again, Applicant is arguing an unrecited limitation in "long-term".

With regard to Applicant's response to the requirement under 37 CFR 1.105 for information, it is noted by the Examiner that Applicant has provided two sets of slides for the Cebon et al material (marked "A2" on Form 1449) presented at Australian Society of Immunology, December 2002, each set having a different number and some overlapping of slides. Both copies have been noted by the Examiner, but they have not been considered on the Form 1449, as the proper number of pages can not be cited. The submission marked "A1" on Form 1449, i.e., the poster, corresponds to the Cebon abstract and slides cited in the Final Rejection mailed 2/3/10.